HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94800d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

JUN 29 2004

WARNING LETTER

FEDERAL EXPRESS

Mr. Massimo Tomasi
President
Simad Medical Technology SRL
Via 25 Aprile 22, P.O. Box 190
I-41037 Mirandola (MO)
Italy

Dear Mr. Tomasi:

During the inspection of your manufacturing facility located in Mirandola, Italy, on March 15-18, 2004, United States Food and Drug investigator, Benjamin J. Dastoli, determined that your firm manufactures the Moonray mobil image x-ray system. This product is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. § 321(h)].

The investigator documented significant violations from the Quality System (QS) regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting regulations, Title 21 CFR, Part 803. These violations cause the device to be adulterated within the meaning of section 501(h) of the Act [21 U.S.C. § 351(h)], in that the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements established by the QS regulation. Additionally, the device appears to be misbranded within the meaning of section 502(t)(2) of the Act [21 U.S.C. § 352(t)(2)], in that there was a failure to comply with a requirement prescribed under section 519.

The inspection resulted in the issuance of a five-point FDA 483 (List of Inspectional Observations) pertaining to medical device reporting procedures, complaint records, in-process testing, and service reports. An evaluation of the FDA 483 items and your firm's written responses to the FDA 483, sent via e-mail on April 22 and May 18, 2004, follows:

Medical Device Reporting (MDR)

1. Your firm failed to develop, maintain, and implement written MDR procedures, as required by 21 CFR § 803.17. Specifically, your firm did not have MDR procedures.

   Your firm's response appears to be adequate: The response included a copy of the newly established "Medical Device Reporting" procedures (#PR012_00; Rev. 00; March 25, 2004), which are found acceptable.

Quality System Regulation

2. Your firm failed to determine whether complaints represent events which must be reported to FDA under part 803, Medical Device Reporting, as required by 21 CFR § 820.198(a)(3). Specifically, your firm's complaint records did not show safety or MDR assessment.

   Your firm's response appears to be adequate: The response included a copy of the revised "After Sale Service – Technical Report" form (#QA93024C_E; Rev. 03; March 16, 2004), which requires MDR assessment.

3. Your firm failed to determine whether an investigation is necessary, as required by 21 CFR § 820.198(b). Specifically, your firm's complaint records did not show if a failure investigation is necessary.

   Your firm's response appears to be adequate: The response included a copy of the revised "After Sale Service – Technical Report" form (#QA93024C_E; Rev. 03; March 16, 2004) and the newly established "Medical Device Reporting" procedures (#PR012_00; Rev. 00; March 25, 2004; page 2), which require the evaluation of all complaints to determine whether an investigation is made.

4. Your firm failed to document acceptance activities, as required by 21 CFR § 820.80(e). Specifically, there was no documentation of in-process testing of the Moonray x-ray device.

   Your firm's response appears to be adequate: The response included a copy of the document "Comunicazione Interna – Inside Communication" (#QA93015A; Rev. 01; No. 122; April 1, 2004), requiring that the in-process testing sheets for the Moonray system be kept as part of the device history record (DHR).

5. Your firm failed to analyze service records to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 CFR § 820.100(a)(1). For example, not all information from service reports was captured by your firm's quality system review. Specifically, only service records from Italy were reviewed for quality problems. Records from the United States and other countries were not reviewed.

   Your firm's response appears to be adequate: The response indicated that all distributors had been advised to communicate all complaints and services with the firm. The response provided an example of what the distributors have to do regarding complaints and services ("After Sale Service – Chinese Market"; March 24, 2004). The response indicated that all service records would be maintained and reviewed for quality problems. The response included a copy of how complaints in Italy have been handled ("Assistenza tecnica Italia anno 2003") and stated that the same procedure would be followed for complaints coming from other countries.

In addition, we have not received annual reports for the Moonray system, as required by 21 CFR § 1002.13. You may download the document "Guide for Filing Annual Reports for X-Ray

Components and Systems" for your use from our web site at http://www.fda.gov/cdrh/radhlth/pdf/xrcrpt0a.pdf.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and applicable regulations. The specific violations noted in this letter and in the list of Inspectional Observations (Form FDA 483) issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. Such action may include the refused entry of your affected products until the corrections are completed.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. You should include all documentation of the corrective action you have already taken, including the information your firm previously sent to the FDA via e-mail on April 22 and May 18, 2004. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement B, Diagnostic Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Ms. Xuan T. Vo.

If you need help in understanding the contents of this letter, please contact Ms. Xuan T. Vo at the above address, telephone (301) 594-4654, or telefax (301) 594-4609.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health